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07/11/2003

Karl F. Popp

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/617,191
Filing Date: July 11, 2003
Appellant(s): POPP, KARL F.

Gary Nath
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9-23-08 appealing from the Office action mailed 2-4-08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

Claims 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,843 to Barody et al.

Instant claims are directed to a process of preparing a composition comprising forming a benzoyl peroxide intermediate dispersion at 15-25 degrees C having a viscosity of 60,000 to 250,000 and a weight of 2.25% to 12.5% benzoyl peroxide in the final product, forming clindamycin intermediate solution having 0.5% to 1.5% clindamycin in the final product and mixing the two to yield a mixture having a final pH of 4.5 to 5.0 and wherein the final viscosity of the mixtures is lower than that of benzoyl peroxide and is between 50,000 to 200,000; and the composition contains sufficient inactive ingredients to provide storage stability for the treatment period.

Barody discloses a composition comprising clindamycin, benzoyl peroxide and a carrier, for the treatment of acne, which is stable for several months, when stored at room temperature and odor free (col. 2, L 3-66). Examiner notes that instant specification equates 22 degrees C to room temperature (last two lines on page 28) and hence Barody teaches stability at the claimed temperature. Barody teaches mixing of a suspension of benzoyl peroxide with a solution of clindamycin salt or ester (col. 2, L 61-64). For the dispersion of benzoyl peroxide see col. 4, L 14-20. Table 1 of Barody shows a composition containing 1% to 20% benzoyl peroxide and 0.2% to 4% clindamycin, and thus includes the claimed amounts of benzoyl peroxide and

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clindamycin. Baroody also teaches the composition having a pH of 4 to <7 and more specifically pH of 4.5-5.5, which meets the instant claimed pH of 4.6 to 4.8 (claim 30). For claim 31, the composition of table 1 does not show the presence of any water. With respect to the loss of clindamycin (claims 28 and 29), Baroody states that the composition is stored at room temperature and remains stable i.e., without substantial loss of the clindamycin content for extended periods of time up to 3 months or longer (col. 7, L 25-30).

With respect to the process of preparing the composition, example 24 of Baroody describes separately preparing clindamycin and benzoyl peroxide components and mixing the two. For the claimed storage stability, while instant claims do not specify any time period, Baroody shows that the composition is stable over a long period of time (table 8) or even up to 4 months (example 24 in col. 17, see L 50-53). Further, examples 10-13 also describe the process of mixing clindamycin solution with a suspension of benzoyl peroxide. Baroody does not teach that the final viscosity is lower than the viscosity of benzoyl peroxide dispersion. However, example 24 shows mixing of clindamycin solution with benzoyl peroxide gel to obtain a homogenous gel. It is the position of the examiner that a mixture of a solution (clindamycin) with a gel (benzoyl peroxide), even though in a final homogenous gel form, implicitly results in a composition of lower viscosity than the initial viscosity of the gel.

Instant claims require that the benzoyl peroxide dispersion has a viscosity of 60,000 to 250,000 cp and that the final viscosity of the mixture has a viscosity lower than the viscosity of the benzoyl peroxide intermediate dispersion, wherein the viscosity

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of the mixture is of about 50,000 to about 200,000 centipoises. Baroody discloses that initial viscosity of benzoyl peroxide is below 90,000 cp, usually is in the range of 50,000 to 90,000 and a final viscosity in the range of 70,000 to 120,000 (col. 5, L 57-64). Thus, the viscosity ranges taught by Baroody overlap with the viscosity ranges of the instant claims. In other words, the initial viscosity of 50,000 to 90,000 cp (Baroody) overlap with the instant initial viscosity of 60,000 to 250,000 cp. Likewise the final viscosity 70,000 to 120,000 cp (of Baroody) overlap with that of the instant final viscosity of 50,000 to 200,000 cp. Baroody also recognizes the same factors i.e., pH, viscosity, concentration of the components etc., as result-affective variables that affect the stability of the composition. In particular, Baroody teaches that viscosity achieved with the gelling agent (such as Carbopol) is a function of pH (col. 6, table 3). Thus, while Baroody teaches that the final composition may have a relatively higher viscosity, Baroody states that the mixture of benzoyl peroxide and clindamycin has an increased pH and therefore a higher viscosity (col. 6, L 3-6). Baroody also suggests that a final pH in the range of 4-7 and more particularly in the range of 4.5 to 5.5, so as to achieve a long-shelf life for the composition, up to several months. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ benzoyl peroxide suspension of appropriate initial viscosity, and mix with clindamycin solution so as to obtain a composition having an optimum final viscosity because Baroody suggests that the viscosity of the final composition is a function of the pH (table 3), which increases with increasing pH. Baroody also suggests that the optimum range of pH is between 4 and less than 7, more preferably between 4.5 and 5.5 (which is

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within the claimed range), at which range the viscosity is lower compared to the viscosity achieved at higher pH levels of 6.0 or 7.0 (table 3). While Baroody suggests an initial relatively low and a final relatively high viscosity levels for easy mixing of the two components (col. 5, 40-56), Baroody also states that the precise weights, volumes, pH levels and the like are all interdependent and should be carefully selected such that the composition possesses desired characters and that the fully prepared composition is stable for a long period of time i.e., 3 months or longer (col. 7, L 18- 30). Accordingly, a skilled artisan would have been able to adjust the initial viscosity of benzoyl peroxide in the claimed range, depending on the amounts of active agents, pH level and the amount of gelling agent with an expectation to achieve a composition of an appropriate viscosity that is stable for long periods of time. While instant claims recite an initial higher viscosity and a final lower viscosity, applicants have not shown the criticality of the initial and final viscosities as a function of stability of the composition.

(10) Response to Argument

Appellants argue that the Examiner has failed to establish a prima facie case of obviousness against the presently rejected claims. To establish a prima facie case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U. S. (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functionsit [may] be necessary for a court to look to interrelated teachings of multiple patents;

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the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issueit can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does..., because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (KSR, *supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494,496 (C.C.P.A. 1970).

Appellants argue that Baroody reference does not teach, disclose, or render obvious any of the presently pending claims because it fails to disclose the requirement of the presently pending claims that the claimed process results in a final composition having a viscosity lower than the viscosity of the intermediate benzoyl peroxide dispersion. It is argued that instead, Baroody actively teaches the exact opposite, requiring the final composition to have a viscosity *higher* than the benzoyl peroxide intermediate composition. Appellants argue that this would motivate one skilled in the art who wishes to invent a storage-stable clindamycin topical composition, to avoid

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taking the opposite relative viscosity between the benzoyl peroxide and the final composition as in the presently pending claims.

Appellants' arguments are not persuasive because as rightly pointed out, in the recent *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U. S., (April 30, 2007), it has been stated that a teaching, suggestion or motivation is required to support a finding of obviousness. The nature of the problem in the instant case as well as the teaching of Baroody is the same i.e., to obtain a composition comprising (same components) benzoyl peroxide and clindamycin that is storage stable for a long period of time, more than 3 months or 4 months or even 18 months or years (see col. 6, L 43-47, col. 7, L 25-31, table 14 and example 24). Under the TSM test, the teaching or suggestion or motivation may be found in the prior art, nature of the problem or the knowledge of one of an ordinary skill in the art. Further, according to *KSR International Co. v. Teleflex Inc. et al.*, "when there is a design need or market pressure to solve a problem and there are a finite number of identified and predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp". In this case, Baroody clearly understands the need to develop a stable composition comprising clindamycin and benzoyl peroxide. Baroody also identified parameters such as viscosity and pH and their importance for the long term stability (col. 3, L 14-36, table 3). In the same section, Baroody describes mixing a suspension of benzoyl peroxide with a solution of clindamycin (which meets the process steps a-c of instant claims) and also state that the viscosity may be relatively low and high, suggesting that it may be varied. Thus, a skilled artisan would have been able to

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determine the optimum levels of viscosity of benzoyl peroxide and that of the final mixture from the teachings of Baroody, such that the composition retains its stability for a long period of time. In addition, while instant claims recite the initial viscosity in the range of 50,000 to 90,000 and a final viscosity in the range of 70,000 to 120,000, instant claims do not recite any duration or length of time over which the composition is stable. On the other hand, the storage stability of the compositions described in the instant specification is no greater than that of Baroody (teaches stability at room temperature up to 4 months).

Appellants argue that Baroody teaches simple mixing of separately maintained clindamycin and benzyl peroxide components, wherein the benzoyl peroxide is in a gel form and that the gelling agent is ideally selected to have a reduced viscosity at the pH of the first component and an increased viscosity at the stage of the final product.

With respect to this argument, it is the examiner's position that when a solution of clindamycin (which has a lower viscosity than benzoyl peroxide suspension with the gelling agent) is mixed with benzoyl peroxide gel, the resulting mixture implicitly has reduced viscosity. Appellant has not shown any evidence to the contrary.

Appellants argue that regarding the viscosities of the benzoyl peroxide suspension and the final product, Baroody et al. further teaches that the lower viscosity of the benzoyl peroxide component makes the combination and mixing with the clindamycin component easier, while the final topical composition can still possess the desired higher viscosity, gel consistency. It is argued that Baroody teaches the

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preferred range of initial and final viscosity (col. 5, L 58-64) and that the resulting product has an increased pH and hence enhanced viscosity that is beneficial (col. 6, L 3-6 and col. 6, L 23-26). Appellants submit that there is no suggestion or motivation to modify the reference to arrive at the instant process. It is argued that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Appellants arguments are not persuasive because while Baroody states that the initial viscosity is "relatively" low than the "relatively" higher final viscosity, Baroody did not teach or state any disadvantages of the opposite i.e., initial high and final low viscosity of the composition. Additionally, with respect to the argument that if the proposed modification or combination of the prior art would change the principle of operation of the prior art being modified, the teachings of the references are not sufficient to render the claims prima facie obvious, In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959), Baroody teaches a range of viscosities (initial and final) and a pH range over which the resulting composition exhibits stability for a long period time. Baroody also provides a teaching to optimize the amounts of clindamycin, benzoyl peroxide, gelling agent, etc., in addition to varying the pH and hence viscosity. Baroody states that in order to primarily achieve the stability of the resulting composition for extended periods of time (months or over a year), the precise weights, volumes, constituent concentrations, pH levels shall be carefully selected because the above factors are interdependent (col. 7, L 18-31).

Appellants' argument that modifying the process of Baroody in an opposite way (with respect to viscosities) would be unsatisfactory because the modification would make mixing harder under the conditions suggested by Baroody.

Appellants' arguments are not persuasive because while Baroody nowhere states that the reverse of viscosities renders mixing harder, Baroody only states the initial and final viscosities are "relatively" low and high, thus, allowing for experimentation such that the stability of the composition is not compromised. Further, the term "relatively" allows for difference of as low as 100 cp or less. On the other hand, the range of viscosities of benzoyl peroxide and final composition recited in the instant claims overlap with the ranges taught by Baroody. Further, while instant claims recite a lower final viscosity, applicants have not provided any unexpected advantage with a lower final viscosity of the composition other than showing that the composition is stable for several months, which is also shown by Baroody. Applicants have not provided any comparative data showing that modifying the viscosities of Baroody to the instant claimed viscosities would render the composition of Baroody unsatisfactory. On the other hand, as mentioned above, Baroody also provides stable composition containing clindamycin and benzoyl peroxide. Additionally, Baroody also states that in admixing the two components, the individual pH of each component is selected carefully such that the final product has a pH that provides stability to the composition. In this regard, once again examiner directs appellants' attention to Table 3 that shows the relation between pH and viscosity. In other words, a skilled artisan would be able to determine the pH and viscosity of the individual components such that not only mixing of the

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components is easier in preparing the composition but also the composition has desired stability and shelf-life for a long period of time. Thus, the primary goal of Baroody is to prepare a stable composition and hence modification of initial and final viscosities as a function of pH of the individual components employed in the composition would have been within the scope of a skilled artisan.

Appellants argue that a prima facie case of obviousness can be rebutted if applicant can show "that the art in any material respect taught away" from the claimed invention. In re Geisler, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997). A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the application. In re Gurley, 31 USPQ2d 1130 (Fed. Cir. 1994). A reference teaches away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. United States v. Adams, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966). It is argued that Baroody repeatedly and expressly teaches gelling agents such that initial viscosity is relatively lower while final viscosity is higher, for easy mixing of the composition.

Appellants' arguments are not found persuasive because while instant comprising language does not exclude the presence of gelling agent of Baroody, a careful review of the instant specification also reveals the preparation of gel as first step, to which benzoyl peroxide and clindamycin are added either together or separately (page 28, L 12-22) such that a stable composition is achieved. In this regard, example

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24 of Baroody also teaches adding a solution and a gel composition. The argument that the reference teaches away is not persuasive because both instant and prior art teachings prepare a composition which has a final pH in the same range as claimed and both compositions exhibit stability for long period of time at room temperature.

Accordingly, a skilled artisan would only be lead to optimize the process such as the viscosity, which in turn is a function of pH, and thus stabilize the composition (of Baroody).

Appellants' argue that instant claims necessarily require that the initial viscosity is higher than the final viscosity and that a person practicing the teachings of Baroody would have been lead in a direction divergent from the path that was taken by the applicant. Appellants argue that the examiner has not given consideration to the teaching away of Baroody and maintained the rejection of record. However, the argument is not persuasive because while instant claims recite initial higher viscosity and final lower viscosity, the claims do not state how high the initial viscosity should be than the final viscosity. Instant claims only recite a range of viscosities that overlap with the ranges described by Baroody. In the instant case appellants have not provided any evidence as to how the initial and final composition is different in terms of viscosities, as compared to that of Baroody. It is the position of the examiner that a mixture of a solution (clindamycin) with a gel (benzoyl peroxide), even though in a final homogenous gel form, implicitly results in a composition of lower viscosity than the initial viscosity of the gel. On the other hand, even though Baroody suggests the relatively low initial viscosity and a relatively high final viscosity, the final composition of Baroody is also

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stable at room temperature and has the same pH range as claimed. Furthermore, Baroody did not suggest any absolute values of viscosities for the initial benzoyl peroxide and final product and instead states that in order to obtain a stable composition at a pH of 4.5-5.5, one need to keep the initial viscosity slightly lower than the higher because carbopol, a gelling agent increases the viscosity with increasing pH (col. 6, L 1-6). A skilled artisan reading the disclosure of Baroody would readily understand that depending on the amount of the ingredients (benzoyl peroxide and clindamycin) in the final composition and the final pH of the composition, one has to vary the amount of gelling agent in the composition such that the pH remains between 4-7 or even between 4.5-5.5 and accordingly, the viscosity also remains at appropriate levels.

Appellants argue that instant process has unexpected advantages as compared to the process disclosed in the Baroody et al. reference, and that this rebuts any alleged prima facie case of obviousness. It is argued that the Baroody et al. reference presents, as a benefit or effect of the process disclosed therein, the facilitation of mixing the two components by selecting a gelling agent to have a lower viscosity in the benzoyl peroxide suspension and a higher viscosity in the final composition. It is argued that Baroody et al. further presents the storage stability of the topical composition prepared according to this procedure for at least one month, for two months, and for three months or longer (col. 5, lines 51-57 and col. 7, lines 25-30). It is argued that the combining of the benzoyl peroxide suspension and the clindamycin solution in the Baroody et al. reference is presented to be done prior to use by a pharmacist. See, id. col. 3, lines 26-

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36. It is argued that in the presently claimed process, the benzoyl peroxide intermediate dispersion has a viscosity of about 60,000 cp to about 250,000 cp and the final composition has a viscosity of about 50,000 cp to about 200,000 cp, wherein the viscosity of the final composition is lower than the viscosity of the benzoyl peroxide dispersion. It is argued that the expected or predictable effect from using viscosities opposite to those disclosed by Baroody et al., as claimed in the present claims, is that it would make the mixing harder, resulting in worse homogeneity of the final composition. Appellants argue that unexpectedly, however, it has been found that the presently claimed process, where the final viscosity is lower than the viscosity of the benzoyl peroxide intermediate dispersion, provides compositions that are easier to mix together, contain less degradates, and have a greater degree of uniformity than those compositions of Baroody.

However, the arguments are not persuasive because while Baroody does not teach an opposite effect i.e., harder mixing by reversing their viscosities, instant application does not provide any comparison of the viscosity ranges taught by Baroody to show that instant viscosity limitation provide unexpected advantage. With respect to the argument regarding the data in Table 8 of Baroody implies that the composition of Baroody is only stable for two months with 90% original clindamycin and 99% benzoyl peroxide. It is argued that instant process with same amount of clindamycin has a minimum projected stability from 7 to 14 months (page 33-34). However, Appellants' arguments are not persuasive because it is not clear from the data on pages 33-34 as to what the initial and final viscosities are. Absent such, a meaningful comparison of

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instant process with that of the prior art cannot be made. Appellants also cite the data in tables 3 and 4 in example 4 for stability over three months and six months. Once again, the experimental details associated with the above data do not provide any information regarding the viscosities of benzoyl peroxide and the final product. On the other hand, appellants also failed to provide a side by side comparison of composition with the claimed viscosities versus that taught by Baroody. While the instant claims recite a range of initial and final viscosities, a composition cannot have a range of viscosity and instead it possesses a single viscosity value. Therefore, the data provided is not commensurate with the scope of the claimed invention.

Appellants finally argue that instant composition no longer requires compounding by the pharmacist at the time of dispensing and hence homogeneity is controlled. It is argued that Baroody does not provide such beneficial properties. However, the argument is not persuasive because in example 24, Baroody clearly states the final mixing of benzoyl peroxide and clindamycin results in a *homogenous* gel. On the other hand, instant claims directed to a process do not recite the argued advantages, a homogenous composition; and hence the arguments are moot.

Therefore the rejection has been maintained.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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